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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/694,519	10/23/00	ISFORT	R 8311

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THE PROCTER & GAMBLE COMPANY
PATENT DIVISION
HEALTH CARE RESEARCH CENTER
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EXAMINER	
STRZELECKA, T	
ART UNIT	PAPER NUMBER
1656	7

DATE MAILED: 05/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Applicati n No.	Applicant(s)	
	09/694,519	ISFORT ET AL.	
	Examiner	Art Unit	
	Teresa E Strzelecka	1656	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-26 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the Restriction Requirement, it is pointed out that applicants have presented claims 16 and 18 in improper format. The claims are improperly joined as the various groups indicated below appear to encompass distinct inventions (administering to a subject a VPAC receptor agonist, a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, an expression vector encoding a functional VPAC receptor, an expression vector encoding a constitutively active VPAC receptor, a compound that increases expression of VPAC receptors, a compound that increases expression of VIP, a compound that increases expression of a VIP analog) to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because these are not proper species.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method for identifying candidate compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a VPAC receptor and determining whether the test compound binds to a VPAC receptor, classified in class 435, subclass 7.1.

II. Claim 2, drawn to a method for identifying therapeutic compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a VPAC receptor, determining whether the test compound binds to a VPAC receptor, administering the test compound to a non-human animal and determining whether the test compound regulates skeletal muscle mass or function, classified in class 435, subclass 7.1.

III. Claims 3-8, drawn to a method for identifying candidate compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a cell expressing a VPAC receptor and determining whether the test compound activates a VPAC receptor, classified in class 435, subclass 7.2.

IV. Claim 9, drawn to a method for identifying therapeutic compounds for regulating skeletal muscle mass or function, comprising contacting a test compound with a cell which expresses a functional VPAC receptor, determining whether the test compound activates a VPAC receptor, administering the test compound to a non-human animal and determining whether the test compound regulates skeletal muscle mass or function, classified in class 435, subclass 7.2.

V. Claim 10, drawn to a method for identifying candidate therapeutic compounds from one or more candidate compounds which have been previously determined to activate VPAC receptor, comprising administering the candidate compound to a non-human animal and determining whether the candidate compound regulates skeletal muscle mass or function, classified in class 435, subclass 7.1.

VI. Claims 11 and 12, drawn to a method for identifying candidate compounds that prolong or augment the activation of a VPAC receptor, comprising contacting a test compound with a cell which expresses a functional VPAC receptor, treating the cell with an agonist and determining the level of activation of the VPAC receptor, classified in class 435, subclass 7.2.

VII. Claim 13, drawn to a method for identifying candidate compounds for increasing VPAC receptor expression, comprising contacting a test compound with a cell or cell lysate containing a reporter gene operatively associated with a VPAC receptor

regulatory element and detecting expression of the reporter gene, classified in class 435, subclass 6.

VIII. Claim 14, drawn to a method for identifying candidate compounds for increasing the expression of VIP or a VIP analog, comprising contacting a test compound with a cell or cell lysate containing a reporter gene operatively associated with a VIP analog regulatory element and detecting expression of the reporter gene, classified in class 435, subclass 6.

IX. Claim 15, drawn to a pharmaceutical composition comprising a safe and effective amount of a VPAC receptor agonist and a pharmaceutically-acceptable carrier, classified in class 514, subclass 1.

X. Claims 16 (in part) and 17, drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a VPAC receptor agonist, classified in class 424, subclass 130.1.

XI. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, classified in class 514, subclass 1.

XII. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective

amount of an expression vector encoding a functional VPAC receptor, classified in class 514, subclass 44.

XIII. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of an expression vector encoding a constitutively active VPAC receptor, classified in class 514, subclass 44.

XIV. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that increases expression of VPAC receptors, classified in class 514, subclass 1.

XV. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that increases expression of VIP, classified in class 514, subclass 1.

XVI. Claim 16 (in part), drawn to a method for increasing skeletal muscle mass or function in a subject, comprising identifying a subject in which an increase in muscle mass or function is desirable and administering to the subject a safe and effective amount of a compound that increases expression of a VIP analog, classified in class 514, subclass 1.

XVII. Claims 18 (in part), 19-21 and 23, drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a VPAC receptor agonist, classified in class 424, subclass 130.1.

XVIII. Claims 18 (in part) and 22, drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that prolongs or augments the activation of VPAC receptors or the activation of a VPAC receptor signal transduction pathway, classified in class 514, subclass 1.

XIX. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of an expression vector encoding a functional VPAC receptor, classified in class 514, subclass 44.

XX. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of an expression vector encoding a constitutively active VPAC receptor, classified in class 514, subclass 44.

XXI. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that increases expression of VPAC receptors, classified in class 514, subclass 1.

XXII. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that increases expression of VIP, classified in class 514, subclass 1.

XXIII. Claim 18 (in part), drawn to a method for treating skeletal muscle atrophy in a subject, comprising identifying a subject in need of treatment for skeletal muscle atrophy and administering to the subject a safe and effective amount of a compound that increases expression of a VIP analog, classified in class 514, subclass 1.

XXIV. Claims 24-26, drawn to a purified antibody specific for the VPAC receptor, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VIII, X-XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

4. Inventions IX and (X and XVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pharmaceutical composition of Group IX could be used for an entirely different purpose such as in the method of Group VI, rather than in the methods of Groups X and XVII.

5. Inventions XXIV and (I-XXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Group XXIV are not required in the methods of Groups I-VIII and X-XXIII, and they are not required to be a part of the composition of Group IX.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

TS
May 22, 2001

TS

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP 1600

5/22/01